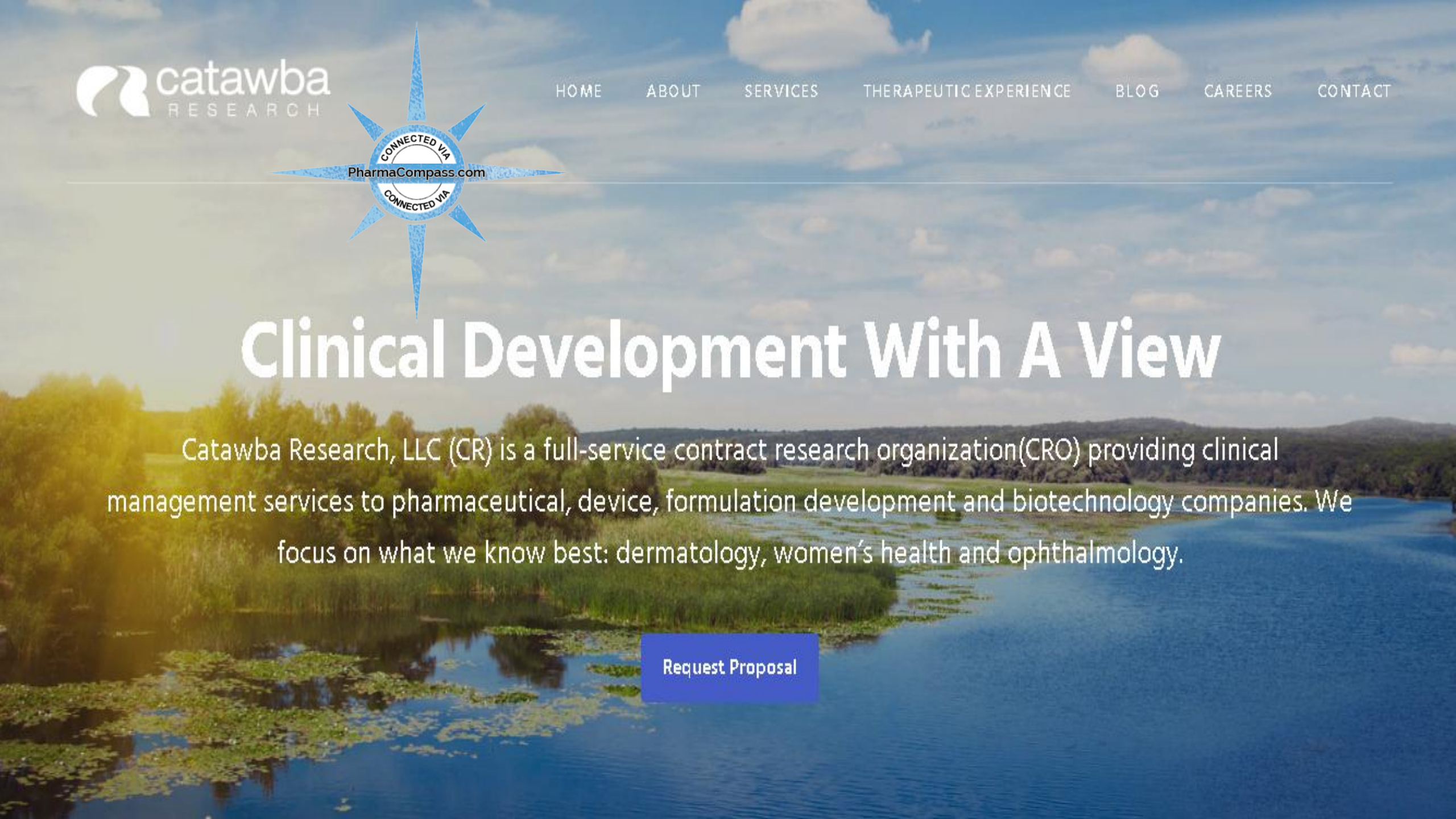
catawba
RESEARCH
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THERAPEUTIC EXPERIENCE
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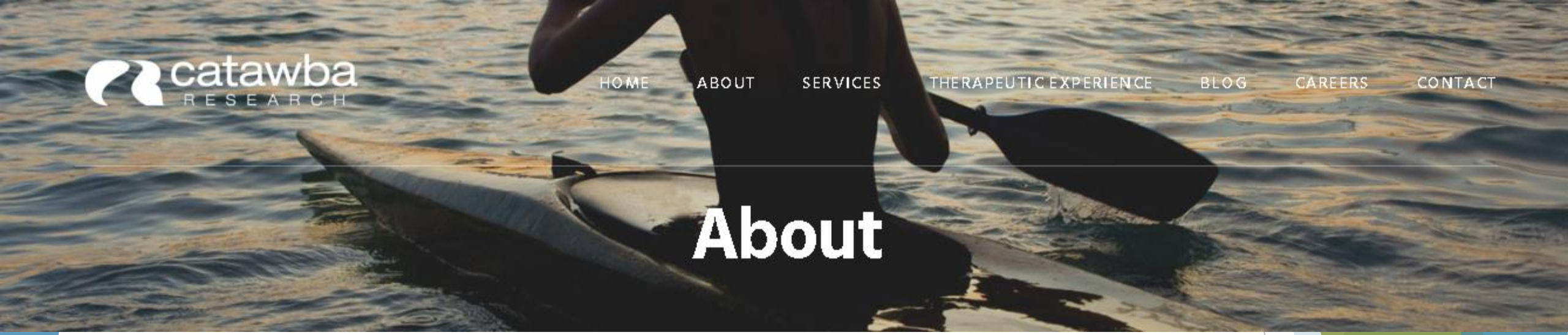
PharmaCompass.com
CONNECTED VIA
Clinical Development With A View
Catawba Research, LLC (CR) is a full-service contract research organization(CRO) providing clinical management services to pharmaceutical, device, formulation development and biotechnology companies. We focus on what we know best: dermatology, women's health and ophthalmology.
Request Proposal

Outline

1. About Us
2. Our Services
3. The Catawba Way
4. Therapeutic Experience
5. Case Study
6. The Catawba Commitment
7. Contact Us



1. **What's in a name?**

   Catawba Research, LLC (CR) is named after the **Catawba River** and the Native American tribes that first settled on the banks. The Catawba River originates in Western North Carolina and is approximately 220 miles (350 km) long. It rises in the Appalachian Mountains and drains into Piedmont.

2. CR is a Charlotte, NC, based CRO focusing on clinical end point trials in patient populations. All members of our team, full time and contractors, have worked together during their careers and have come together to create a solid structure for performing top level research.

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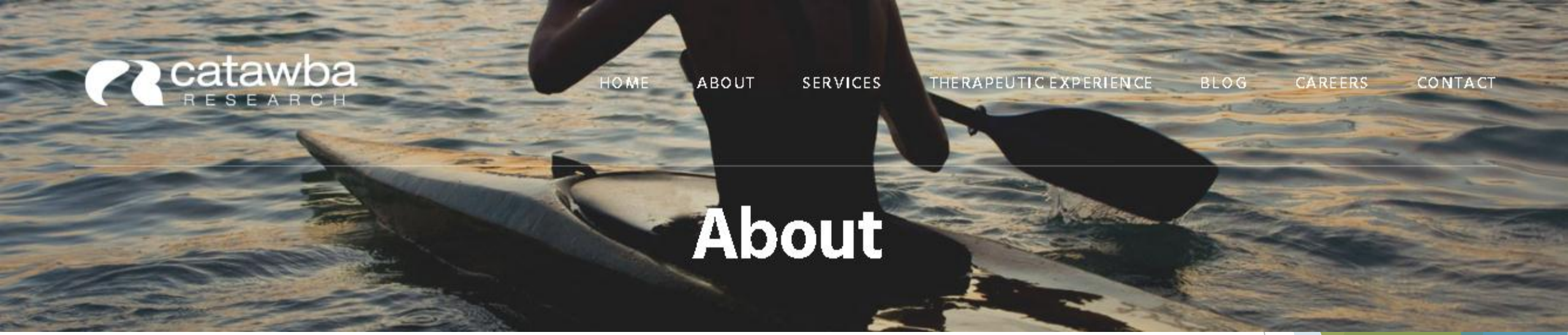

3. People and Culture

"If I owned a CRO, what kind of company would I create?"

- 10 Employees
- Currently Over 15 Contractors
  - Flexible to increase or reduce to fit organizational need
- At anyone time, Catawba employs approximately 25 clinical development professionals

- Work Life Balance
  - Employees have the choice to work remotely or from the office
  - CRAs are regionally based. This also helps to reducing monitoring travel costs

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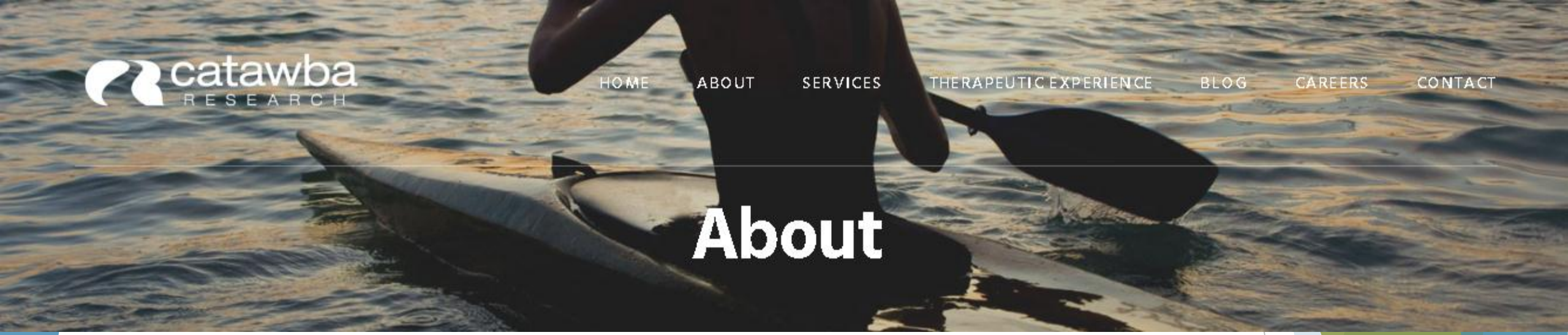

CATAWBA RESEARCH, LLC

September 2014
- Scientific Affairs
- Regulatory Affairs

CATAWBA CLINICAL RESEARCH, LLC

2015
Awarded 6 Trials
- 4 ANDAs
  (2 First To File)
- 2 Rescue

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2016 (to date)
Awarded 10 Trials
- 6 ANDAs
  (2 First To File)
- 1 Canadian submission
- 3 505(b)(2)

- Move to a new location
- Rebrand
  (new website & logo)
  www.catawbaresearch.com

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2017 (anticipated)
- 12 - 16 Trials
- ANDAs and 505(b)(2)

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Services

- Scientific and Regulatory Affairs
- Study Management
- Project Management
- Clinical Operations & Monitoring
- Site Management
- Quality Assurance
- Data Management, Biostatistics and Medical Writing

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Site Selection

- High Enrolling Sites
- Quality Clinical Research Centers
- Patient Population
- Control Variability
- Site Metrics

Project Control

- Streamlined Start-up
- Efficient Timelines
- Efficient Operations
- Recruitment Planning
- Risked-Based Monitoring

Cost Efficient

- On-time Delivery
- Project Scope Control
- Vendor Management
- Patient Retention
- Minimize Enrollment Numbers

The Catawba Way

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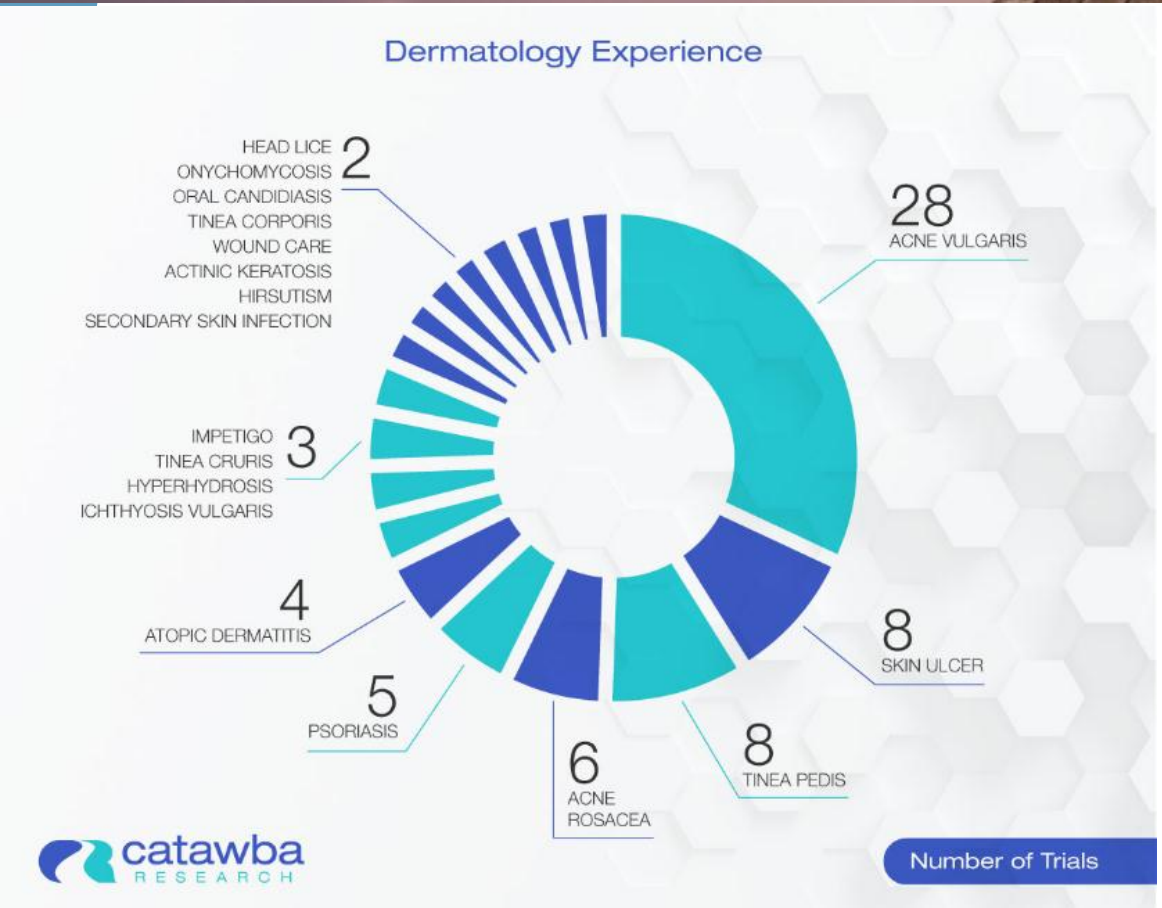

Catawba Research, LLC (CR) team has worked in the area of dermatology for over 15 years and has worked on over 80 (and counting) clinical trials for many marketed products. Many of these products were critical for development decisions so our team has a deep understanding of streamline trial execution for ensuring timelines are met.

With this experience comes expertise in the execution of trials in dermatology and the understanding the challenges that impact patient enrollment with each indication.

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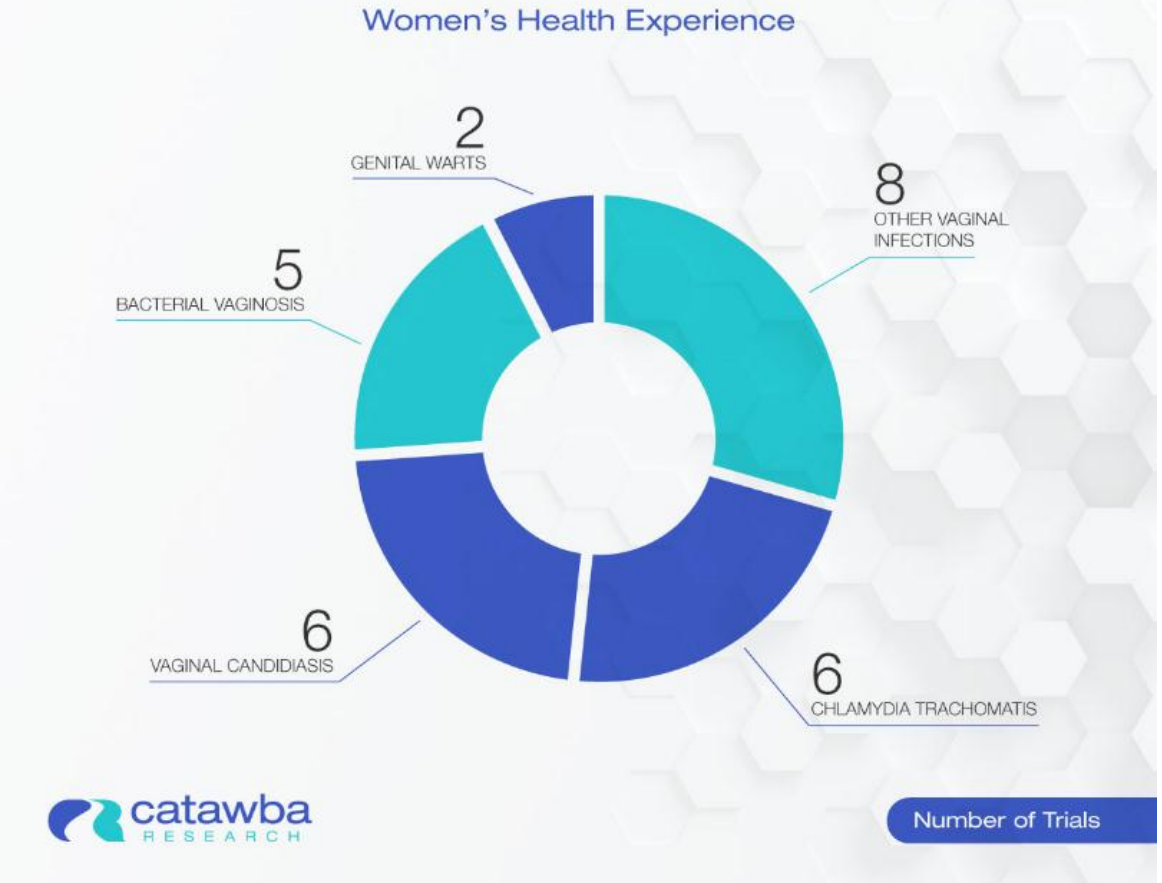

Catawba Research holds a solid track record in the area of women's health and reproduction. The reason for this is simple: We have conducted well-designed and highly efficient studies on both biologics and small molecule drugs, in every phase and in numerous indications.

Our expertise in this therapeutic space includes yeast infections, genital warts, and bacterial vaginosis (BV) clinical trials, to name a few. Catawba Research is knowledgable with the challenges inherent in women's health clinical research and the solutions needed to run a successful program.

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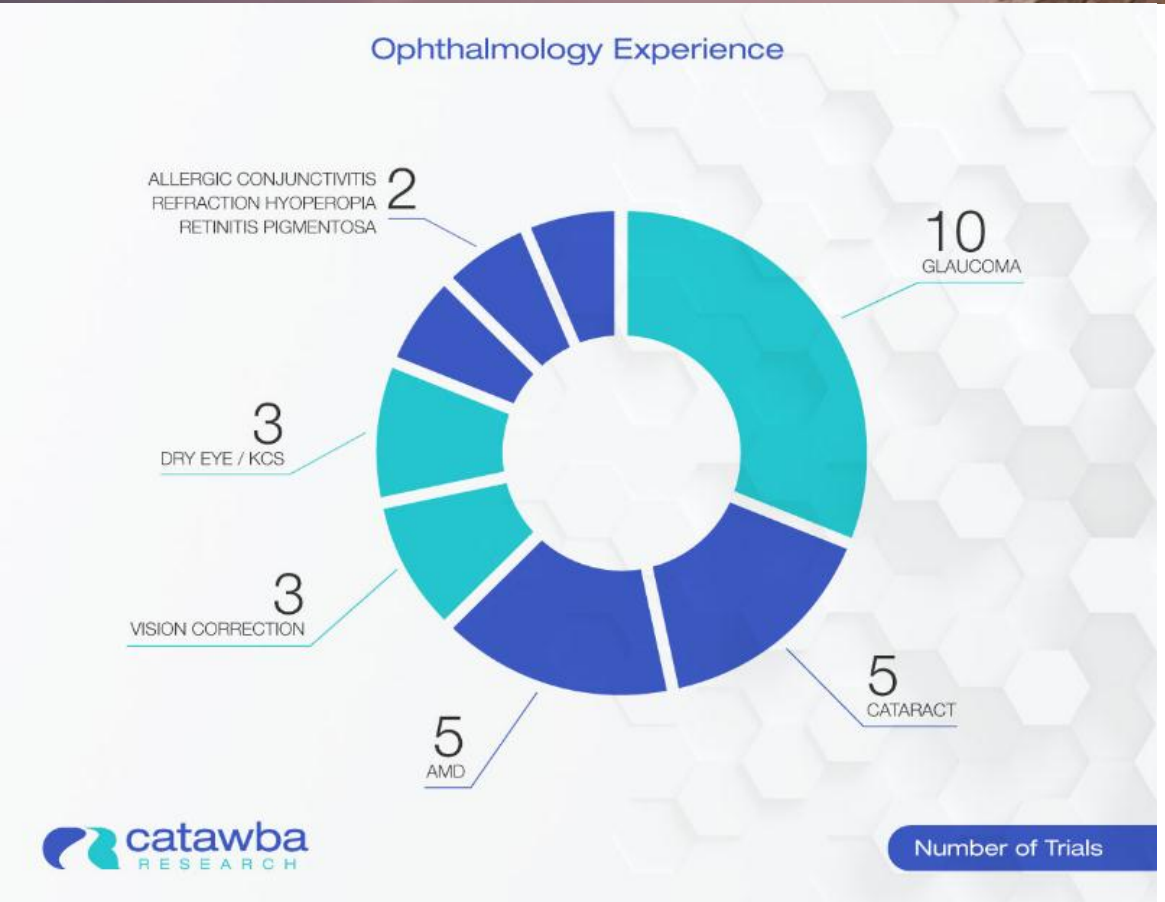

Our outstanding reputation in the pharmaceutical industry rides on steady, consistent performance; in-depth research proficiency; unfailing emphasis on the patient; accurate and meticulous data; and on-deadline results.

As a leading ophthalmology CRO, the team at Catawba Research brings considerable experience in various ophthalmology clinical research programs including cataracts, glaucoma, AMD, and more.

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Case Study 1

Objectives:
To demonstrate the superiority of the efficacy of the test and reference products over the placebo control in the treatment of **acne vulgaris.**

Design:
A multi-center, randomized, double blind, parallel, placebo controlled, in vivo.

Case Study 1

Treatment Duration:
The study treatment period lasted for 12 weeks

Number of Subjects:
Approximately 840 subjects.

Criteria for Evaluation:
Primary Endpoints:

1. Percent change from baseline to week 12 in the inflammatory lesion counts and;
2. Percent change from baseline to week 12 in the non-inflammatory lesion counts.

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Case Study 1

PROJECT DETAILS	
Number of subjects:	840
Number of sites:	10
Product at site:	Month 1
FSFV:	Month 1
LSLV:	Month 5
Final eCTD CSR:	Month 6
Total Timeline:	6 Months

Case Study 1

PROJECT DETAILS	
Primary endpoint	✓
Secondary endpoint:	✓
Budget:	✓
Time line:	✓

Case Study 2

Objectives:
To demonstrate the superiority of the efficacy of the test and reference products over the placebo control in the treatment of **rosacea**.

Design:
A multi-center, randomized, double blind, parallel, placebo controlled, in vivo.

Case Study 2

Number of Subjects:
Approximately 1000 subjects.

Criteria for Evaluation:
Primary Endpoints:
Percent change from baseline to week 12 in the inflammatory (papules and pustules) lesion counts.

Secondary Endpoints:
An Investigator's Global Evaluation (IGE) should be evaluated as a secondary endpoint

Case Study 2

PROJECT DETAILS	
Number of subjects:	1000
Number of sites:	33
Product at site:	Month 1
FSFV:	Month 1
LSLV:	Month 8
Final eCTD CSR:	Month 9
Total Timeline:	9 Months

Case Study 2

PROJECT DETAILS	
Primary endpoint	✓
Secondary endpoint:	✓
Budget:	✓
Time line:	✓

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The Catawba Commitment

HQ Office

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